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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,770	10/29/2003	Kary B. Mullis	13139-0103 (13721.105005)	7920
20786 7590 01/17/2008 KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309-3521				
EXAMINER SAUNDERS, DAVID A				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/696,770

Applicant(s)

MULLIS, KARY B.

Examiner

David A. Saunders

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 10-16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 10-16 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **AMENDMENT ENTRY**

Amendment of 5/17/07 has been entered. Claims 1-4, 7, 10-16 and 18 are pending. And are under examination.

## **OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN**

The amendment has overcome previously stated issues as follows:

The rejection of claim(s) 1 and 18 under 35 USC 112, 2<sup>nd</sup> paragraph.

The prior art rejection of claim(s) 1-2,4,7,13 and 18 based upon Salberg. Salberg does not disclose the use of any composition corresponding to an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18.

The prior art rejection of claim(s) 1-2; 13 and 18 based upon Krsmanovic. Krsmanovic does not disclose the use of any composition corresponding to an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18. Furthermore, the reference does not contemplate (col. 5, lines 15-21) any kind of conjugate that has a linkage constructed by a genetic engineering method (e.g. as in a fusion polypeptide/protein).

The prior art rejection of claim(s) 1-3,5,13 and 18 based upon Marinkovich. Marinkovich does not disclose the use of any composition corresponding to an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18. Furthermore, the reference does not contemplate (para. [0060]-[0074]) any kind of conjugate that has a linkage constructed by a genetic engineering method (e.g. as in a fusion polypeptide/protein).

The prior art rejection of claim(s) 1-7 and 12-18 based upon Pouletty. Pouletty does not disclose the use of any composition corresponding to an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18.

The prior art rejection of claims 1-2,4-7,12-13 and 18 based upon Low et al. Low et al does not disclose the use of any composition corresponding to an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage

and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18. Furthermore, the reference does not contemplate (col. 9, lines 34+) any kind of ligand-immunogen conjugate that has a linkage constructed by a genetic engineering method (e.g. a fusion polypeptide/protein).

The prior art rejection of claims 1-2,5-6,13-14 and 18 based upon Cowan et al. Cowan et al does not disclose the use of any composition corresponding to an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18. Furthermore, the reference does not contemplate (pages 10-15) any kind of hapten-ligand conjugate that has a linkage constructed by a genetic engineering method (e.g. a fusion polypeptide/protein).

The 103 rejection of claims 1 and 16-17 under 35 USC 103 over Marinkovich, Poulety, Low et al or Cowan, any or all in view of Rhodes. As noted supra, none of the primary references teach the limitations of base claim 1.

The obviousness type double patenting rejection of claims 1-18 over claims 8 and 10-13 of copending application 10/178,046. This copending application has been abandoned and has been refilled as application 11/606,564, which has no claims which recite an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18. Furthermore no generic claim of copending application 11/606,564 can be considered as encompassing an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, because no such linker is disclosed in application '564.

The obviousness type double patenting rejection of claims 1-17 over claims 1-19 of copending application 10/754,756. This copending application has no claims which recite an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage, as required by instant claims 1 and 18. Furthermore, the broadest method claim of copending application 10/754,756 cannot be considered as encompassing an immunity linker that has a first binding site comprised of a first polypeptide expressed by a bacteriophage and a second binding site comprised of a second polypeptide expressed by a bacteriophage.

**MAINTAINED REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, line 3-4, references to "different epitopes of a component of the immune response" are unclear, because any "components of the immune response" would not be understood by one of skill as having any "epitopes". It is taken that "the immune response component" can be an antibody or a T/B cell receptor (see para. [0143] of applicant's disclosure in US 2004/0146515). It is well known in the art that these antibodies or T-cell receptors would recognize B or T epitopes on the antigenic components serving as "the first binding sites". The "epitopes" are thus on "the first binding sites", rather than on a "component of the immune response".

Applicant's amendment has necessitated the following new ground(s) of rejection.

**NEW REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, line 1 "the first bacteriophage" lacks antecedent basis.

**NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH**

Claims 1-4,7,10-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 18 recite new matter.

Specifically, claims 1 and 18 pertain to a method in which an immunity linker is described such that "the first binding site comprises a first polypeptide expressed by a bacteriophage and the second binding site comprises of a second polypeptide expressed by a bacteriophage". Because each recitation of "bacteriophage" is preceded by the article "a", the claim language does not require that the second recited "bacteriophage" be the same as the first recited "bacteriophage". The original disclosure, however, was more limited in scope because the teachings did require that the "bacteriophage" expressing the "first polypeptide" and the "bacteriophage" expressing the second polypeptide be the same "bacteriophage". Applicant has thus opened the scope of the claims to encompass the case in which an immunity linker could be comprised of two bacteriophages that have been chemically conjugated to each other, wherein the first "bacteriophage" is one expressing the "first polypeptide" and the second "bacteriophage" is one expressing the "second polypeptide". No such immunity linker constructed of two different bacteriophages was originally contemplated. Note particularly original claims 8-9, wherein claim 9 refers to "the bacteriophage" at lines 2 and 4: thus the "first polypeptide" and the "second polypeptide" were expressed by the same "bacteriophage". Likewise note para. [0035] of US 2004/0146515.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent Claim 1 has been amended to recite the use of an immunity linker that is a bacteriophage, that expresses a first and a second polypeptide that serve, respectively, as a first and a second binding site. In dependent claim 12, the "first binding site" is required to be "an alpha-galactosyl epitope", which is a carbohydrate, rather than a polypeptide. It would thus not be possible for one to express "an alpha-galactosyl epitope", which is a carbohydrate, in the bacteriophage used in the method of base claim 1.

#### **ART OF INTEREST**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Salberg et al (6,933,366) is cited as of interest. This reference expands upon the disclosure of Salberg (US 5,869,232 or WO 95/29938 of record). This reference makes a brief reference to recombinant bacteriophages at col. 17, lines 10-24. Therein the recombinant bacteriophages are used to transform bacterial cells; and it is the transformed bacterial cells, not recombinant bacteriophages particles, which express the fusion polypeptides

## **FINALITY**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

## **CONTACTS**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 1/14/08 DAS

A handwritten signature in cursive script, reading "David A. Saunders".

DAVID A. SAUNDERS  
PRIMARY EXAMINER